(12) UK Patent Application (19) GB (11) 2 423 267 (13) A

(43) Date of A Publication 23.08.2006

(21) Application No: 0503415.2

(22) Date of Filing: 18.02.2005

(51) INT CL:
C09J 7/02 (2006.01) A61F 13/02 (2006.01)
A61L 15/58 (2006.01)

(52) UK CL (Edition X):
B2E EL E1538 E1733 E1739 E436S E438T E438U E441S E473S E474S E491S
U1S S1049

(56) Documents Cited:
EP 0955347 A FR 002735024 A

(58) Field of Search:
UK CL (Edition X) B2E
INT CL[7] A61F, A61L, C09J
Other:

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(54) Abstract Title: **Adhesive pad for a medical device**

(57) An adhesive pad for securing a medical device, such as an ostomy appliance, urine leg bag or wound and fistula management products or products to contain the output of highly exuding wounds, to a body surface of a patient, comprises an interfacing layer 6, a layer of silicone bioadhesive 2 and a release liner 4 for the adhesive; one side of the interfacing layer defining a thermoplastic surface 8 capable of being bonded to a medical device and the opposing surface 10 of the interfacing layer having been primed or otherwise treated to enable the opposing surface to bond to the silicone bio-adhesive. The opposing surface may be subjected to modification by plasma treatment, which may be carried out in the presence of polydimethylsiloxane, or corona discharge treatment. Alternatively the surface 3 may have a coating of primer 10 such as silicone oil e.g. polydimethylsiloxane.

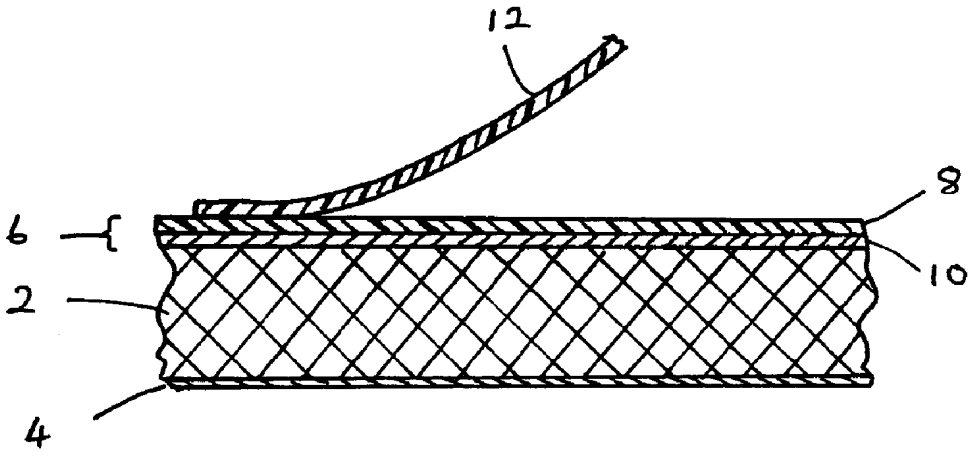

FIG. 1

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

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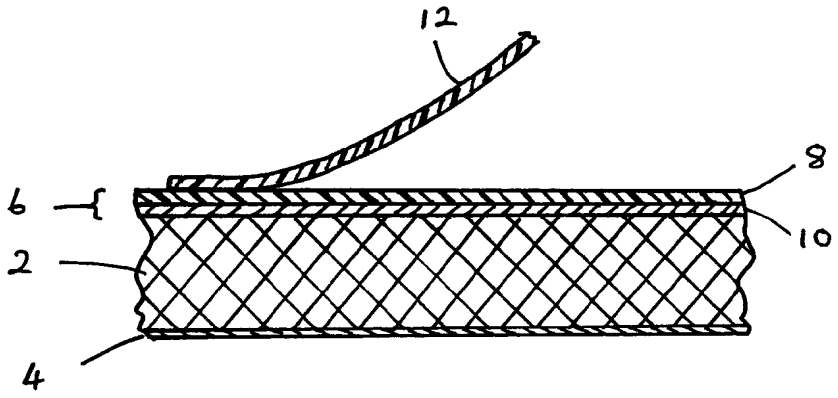

FIG. 1

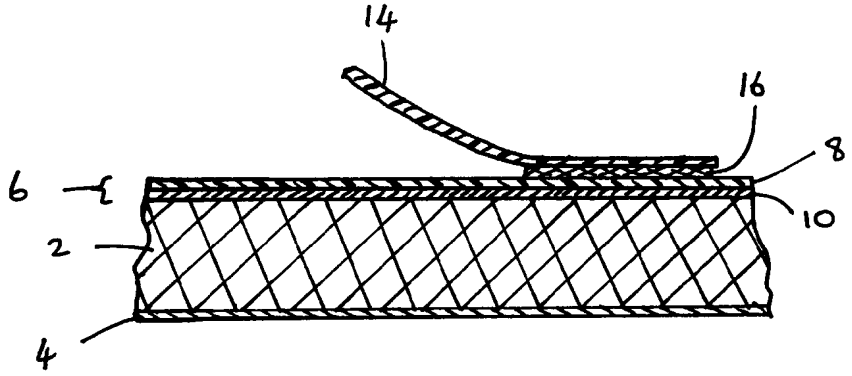

FIG. 2

ADHESIVE PAD FOR A MEDICAL DEVICE

This invention relates to an adhesive pad for securing a medical device to the body of a patient, and to medical devices provided with the adhesive pad.

Background of the Invention

Many devices are externally attached to the body, using a variety of adhesives. In many situations the adhesive performance is unsatisfactory and /or the skin is damaged by frequent removal and replacement of the device.

Where the adhesive is attached to relatively intact skin, the main insult to the adhesive is trans-epidermal water loss. In many circumstances, sufficient absorbency capacity can be built into the adhesive by the incorporation of materials such as gelatin and carboxymethyl cellulose, increasing the thickness of the adhesive and/or providing a porous backing to permit transpiration of water vapour to the atmosphere.

However there are many situations where the skin is not intact and where the quantity and nature of the exudate or secretion is such that a more effective means of attachment is required. Typical examples include ostomy appliances for ileostomy, colostomy and urostomy, urine leg bags, wound and fistula management products and products to contain the output of highly exuding wounds such as burns, leg ulcers and some carcinomas.

The difficulty in these applications is that the volume and nature of the exudates can quickly overwhelm traditional adhesives such as hydrocolloid adhesives. Conventional hydrocolloid devices use slabs of hydrocolloid of considerable thickness in an attempt to provide additional capacity. These remain ineffective as adhesives, are difficult to customise to the needs of the user, are uncomfortable to wear and are relatively expensive to produce.

Hydrocolloid adhesives typically absorb liquid exuding from a wound or stomal opening and swell until a point is reached where hydrocolloid begins to dissolve and break down. As the hydrocolloid dissolves, so the adhesion between the

adhesive pad and skin of the patient progressively diminishes until there is no longer sufficient adhesion to adhere the medical device to the patient. Some hydrocolloid adhesives ("integrated hydrocolloid") contain a cross-linked matrix which swells rather than dissolves but a problem here is that once the liquid absorbent capacity of the matrix is exceeded, the adhesion to the patient fails shortly thereafter.

Some 'wet-stick' adhesives are available which are based on synthetic materials such as modified acrylics or rubbers and such adhesives typically contain an absorbent substance such as a hydrocolloid, starch, pectin or carboxymethylcellulose to absorb excess liquid. However, a problem with such adhesives is that they can be difficult to remove and have been shown in many instances to cause damage to already compromised skin.

Accordingly, there exists a need for an adhesive which bonds effectively to the skin, is easy to remove, is inert (i.e. is chemically unreactive towards the skin and doesn't form chemical bonds with skin components), is non-irritating to the skin and resists attack by moisture. Such an adhesive should be capable of being frequently re-applied and removed from the same area of skin.

A further requirement of an adhesive used for the purposes of adhering a medical device to the skin is that it is clearly necessary to be able to secure the other components of a medical device (for example ostomy and urine collection bags or a tube attachment device) to the reverse surface of the adhesive layer. Techniques used in attaching an adhesive pad to a medical device typically include welding (e.g. by means of heat, or by RF or ultrasonic welding) or adhesives (e.g. double sided pressure sensitive adhesive tapes (for example based on acrylics), UV cured systems and cyano-acrylates).

Silicone based adhesives have the characteristics of good adhesion in the presence of moisture and skin friendliness; they can be formed from polydimethyl-siloxane and cross-linked using a catalyst. Highly moisture resistant, and inert in terms of interaction with the body, they can also be removed easily with minimum trauma.

However, silicone adhesives have proved difficult to use in medical devices because of their inertness and the impossibility of welding them directly to materials such as PVC, EVA, polyethylenes and polyamides (e.g. Nylon) using traditional welding methods. The direct attachment of silicones to other adhesives has also proved problematical.

Summary of the Invention

It has now been found that the aforementioned problems can be overcome, in the context of medical devices for attachment to the human or animal body, by interposing between a medical device and a silicone adhesive an interface layer having one surface of a thermoplastic nature and an opposing surface having physicochemical properties that enable it to bond to silicones.

In a first aspect, the invention provides an adhesive pad for securing a medical device to a body surface of a patient; the adhesive pad comprising an interfacing layer; a layer of silicone bio-adhesive and a release liner for the adhesive; one side of the interfacing layer defining a thermoplastic surface capable of being bonded to a medical device, and the opposing surface of the interfacing layer having been primed or otherwise treated to enable the said opposing surface to bond to the silicone bio-adhesive.

The thermoplastic surface of the interfacing layer is provided by a thermoplastic polymer and is capable of being welded or adhesively bonded to a medical device, for example a medical device of the type hereinbefore defined.

The thermoplastic polymer can be for example a polyolefin such as polyethylene or polypropylene, a polyamide (e.g. "Nylon"), polyurethane, polyvinylchloride or ethylene-vinyl acetate copolymer (EVA).

The interfacing layer may consist of a single layer of polymer, or it may have a laminar form made up from two or more individual polymer layers which may be the same or different. In one embodiment, the interfacing layer is defined by a single layer of thermoplastic polymer. In a second embodiment, the interfacing

layer is defined by a laminate of two polymer films, for example a laminate comprising a layer of polyolefin such as polyethylene and a layer of a polyurethane.

The opposing surface of the interfacing layer is primed or otherwise treated to enable it to bond to the silicone bio-adhesive. For example, the surface may be subjected to modification by plasma treatment or corona discharge treatment to enhance its adhesion to the silicone bio-adhesive. In one embodiment, plasma treatment may be carried out in the presence of polydimethylsiloxane in order to introduce siloxane groups on to the surface of the polymer.

Alternatively, and currently more preferably, the surface may have a coating of a primer that facilitates bonding to the silicone adhesive. The primer can be, for example, a thin layer, e.g. a monolayer, of a silicone oil such as a polydimethylsiloxane fluid. A particular example of a silicone oil primer is Rhodorsil ® manufactured by Rhodia Silicones of Cranbury, NJ, USA.

Examples of thermoplastic polymer films having one surface defined by a thermoplastic polymer and an opposing surface which is capable of bonding to a silicone adhesive are the "Epurex" polymer films supplied by Bayer, of Leverkusen, Germany. Particular "Epurex" polymer films are the "Walotex" films and in particular the "Walotex" films such as Walotex grade U073 which consist of a polyurethane layer and a polyethylene carrier layer.

The silicone adhesive is a bio-adhesive, i.e. it is an adhesive that is capable of bonding to body surfaces such as skin and is non-toxic when applied to such surfaces. It is preferably removable, and is typically a pressure sensitive adhesive.

The silicone adhesive may comprise, for example, a cured silicone rubber. The rubber may contain an oil such as a silicone oil.

In one embodiment, the silicone adhesive comprises a polydimethylsiloxane. The polydimethylsiloxane may be cured, i.e. crosslinked, but the extent of cross-linking is such that the polymer has a degree of tackiness appropriate for an adhesive. The polydimethylsiloxane may contain silicone oil.

One example of a silicone adhesive is Silbione® available from Rhodia Silicones.

Typically, substantially the entire adhesive surface area on the bodyside surface of the pad, i.e. the side of the pad intended to be secured to the body surface of a patient, comprises a silicone adhesive. However, where part of the adhesive surface area on the bodyside surface of the pad is formed by a non-silicone containing adhesive, the non-silicone containing part typically forms less than 50% of the total adhesive surface area, more typically less than 40%, 30%, 20%, 10% or 5% of the total adhesive surface area.

The term "total adhesive surface area" as used herein refers to the total area of adhesive (whether silicone containing or non-silicone containing) available on the adhesive pad, after any release liners have been removed, for securing the medical device to the body surface of the patient.

In a further aspect, the invention provides an adhesive pad as hereinbefore defined, the adhesive pad having a medical device bonded to the thermoplastic surface thereof.

The invention will now be illustrated, but not limited, by reference to the specific embodiments shown in the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a schematic sectional elevation of part of an adhesive pad according to one embodiment of the invention, an element of a medical device having been welded to the pad.

Figure 2 is a schematic sectional elevation of part of the adhesive pad of Figure 1 but with an element of a medical device adhesively bonded to the pad rather than welded.

Detailed Description of the Invention

Figure 1 illustrates an adhesive pad according to one embodiment of the invention. As shown in Figure 1, the adhesive pad comprises a layer of silicone adhesive 2,

which can be an adhesive sold under the trade name Silbione ® by Rhodia, with a peelable release liner 4 attached to one surface. Attached to the other surface of the silicone adhesive is an interfacing layer 6 which consists of a layer 8 of a thermoplastic polymer such as polyethylene, polyurethane or a polyurethane/polyethylene laminate and a thin layer 10 of a silicone primer. The primer layer 10, the thickness of which is exaggerated in the drawings, enables the adhesive 2 to be firmly bonded to the thermoplastic polymer layer 8.

The thermoplastic polymer layer 8 can then be bonded to a thermoplastic element 12 of a medical device such as an ostomy bag or wound drainage bag by a conventional welding technique such as RF welding, thermal welding or ultrasonic welding. The thermoplastic element 12 can take the form of a film, fabric or net, for example, but can also be a moulding such as the body side portion of a two piece ostomy appliance.

As an alternative to welding, an element 14 of a medical device can be adhesively bonded to the thermoplastic layer 8 by a layer of adhesive 16. Examples of adhesives include PVA, polyurethane adhesives, hot melt polymers, acrylic adhesives and cyanoacrylates. When an adhesive is used, the element 14 can be formed from a thermoplastic or non-thermoplastic material. Examples of non-thermoplastic materials include non-woven, knitted and woven fabrics and paper.

The adhesive pads of the invention can be manufactured by coating the uncured silicone adhesive continuously or discontinuously onto the primed surface 10 of the interfacing layer. This can be achieved by a variety of techniques including printing, casting or spreading using a spreader such as a doctoring blade. The uncured adhesive is then left to cure and a suitable release paper or film is then applied to protect the adhesive.

It will be appreciated from the foregoing that the invention enables silicone adhesives to be used for adhering medical devices such as ostomy bags and wound drainage bags to the human body thereby overcoming the problems associated with the conventional hydrocolloid adhesives currently used for this purpose.

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Equivalents

It will readily be apparent that numerous modifications and alterations may be made to the specific embodiments of the invention described above without departing from the principles underlying the invention. All such modifications and alterations are intended to be embraced by this application.

CLAIMS

1. An adhesive pad for securing a medical device to a body surface of a patient; the adhesive pad comprising an interfacing layer; a layer of silicone bio-adhesive and a release liner for the adhesive; one side of the interfacing layer defining a thermoplastic surface capable of being bonded to a medical device, and the opposing surface of the interfacing layer having been primed or otherwise treated to enable the said opposing surface to bond to the silicone bio-adhesive.

2. An adhesive pad according to claim 1 wherein the interfacing layer is coated with a primer to enable the said opposing surface to bond to the silicone bio-adhesive.

3. An adhesive pad substantially as described herein with reference to the accompanying drawings.

4. A medical device such as an ostomy bag or wound drainage bag, the medical device being provided with an adhesive pad as defined in any one of the preceding claims.

INVESTOR IN PEOPLE

Application No: GB0503415.2 **Examiner:** Robert Mirams

Claims searched: 1 to 4 **Date of search:** 4 May 2005

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	n/a	EP0955347 A (DOW CORNING FRANCE) whole document
A	n/a	FR2735024 A (SANOFI) whole document

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[X] :

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Worldwide search of patent documents classified in the following areas of the IPC[07]

A61F; A61L; C09J

The following online and other databases have been used in the preparation of this search report

WPI,EPODOC,JAPIO